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\$	App	olication Number	10/086	5,913
TRANSMITTAL	Filin	ng Date	March	1, 2002
FORM		st Named Inventor	Higuch	ni, et al.
		Unit	1652	
(to be used for all correspondence after initi		aminer Name	Maryar	nn Monshipouri
Total Number of Pages in This Submission	Atto	orney Docket Numbe	o68528	8.0103
	ENCLOS	URES (Check	all that app	oly)
Fee Transmittal Form	Drawin	•		After Allowance Communication to TC  Appeal Communication to Board
Fee Attached		sing-related Papers		of Appeals and Interferences
Amendment/Reply  After Final  Affidavits/declaration(s)  Extension of Time Request  Express Abandonment Request	Provis Power Chang Termin	on to Convert to a sional Application r of Attorney, Revoca ge of Correspondence inal Disclaimer est for Refund		Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)  Proprietary Information  Status Letter  Other Enclosure(s) (please Identify below):
Information Disclosure Statement		lumber of CD(s) Landscape Table on	CD	-
Certified Copy of Priority Document(s)  Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53	Document(s)  Reply to Missing Parts/ Incomplete Application			
SIGN	ATURE OF A	PPLICANT, ATT	TORNEY,	OR AGENT
Firm Name Baker/Botts LLP	1	Custome	er No. 21(	003
Signature	M			
Printed name Lisa B. Kole		·	· · · ·	
Date 10/17/2005	7.5		Reg. No.	35,225
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Higuchi et al.

Examiner: Maryam Monshipouri

Serial No.

10/086,913

Group Art Unit: 1652

Filed

March 1, 2002

For

PREVENTION AND TREATMENT OF MYCOPLASMA-

ASSOCIATED DISEASES

Customer No.:

21003

## SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

## EXPRESS MAIL NO. ED 292754610US

Commissioner for Patents Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, Applicants respectfully request that the documents listed below and on the accompanying PTO 1449 be considered by the Examiner and made of record in the above-referenced application. Copies of the listed documents are enclosed.

- 71. Kaji M et al., 2005, "A side effect of neuraminidase inhibitor in a patient with liver cirrhosis," J. Infect. Chemother. 11:41-43.
- 72. Amaya MF et al., 2004, "Structural insights into the catalytic mechanism of *Trypanosoma cruzi* trans-sialidase," Structure 12:775-784.
- 73. Higuchi ML et al., 2004, "*Trypanosoma cruzi* trans-sialidase as a new therapeutic tool in the treatment of chronic inflammatory diseases: possible action against mycoplasma and chlamydia," Medical Hypothesis 63:616-623.

- 74. Higuchi ML et al., 2003, "Coinfection with *Mycoplasma pneumoniae* and *Chlamydia pneumoniae* in ruptured plaques associated with acute myocardial infarction," Arq. Bras. Cardiol. 81(1):12-22.
- 75. Higuchi ML et al., 2003, "Pathophysiology of the heart in Chagas' disease: current status and new developments," Cardiovasc. Res. <u>60</u>: 96- 107.
- 76. Watts AG et al., 2003, "*Trypanosoma cruzi* trans-sialidase operates through a covalent sialyl-enzyme intermediate:tyrosine is the catalytic nucleophile," J. Am. Chem. Soc. 9(25): 7532-7533.
- 77. Aiello VD et al., 2002, "A possible role for complement in the pathogenesis of chronic chagastic cardiomyopathy," J. Pathol. <u>197</u>:224-229.
- 78. Buschiazzo et al., 2002, "The crystal structure and mode of action of transsialidase, a key enzyme in *Trypanosoma cruzi* pathogenesis," Molecular Cell <u>10</u>:757-768.
- 79. Dallo SF et al., 2000, "Intracellular DNA replication and long-term survival of pathogenic mycoplasmas," Microb. Pathog <u>29</u>:301-309.
- 80. Palomino AS et al., 2000, "Systematic mapping of hearts from chronic chagasic patients: the association between the occurrence of histopathological lesions and *Trypanosoma cruzi* antigens," Ann. Trop. Med. Parisitol. 94(6):571-579.
- 81. Treanor JJ et al., 2000, "Efficacy and safety of the oral neuraminidase inhibitor oseltamivir in treating acute influenza: a randomized controlled trial. U.S. oral neuraminidase study group," JAMA 283(8):1016-1024.
- 82. Monto AS et al., 1999, "Efficacy and safety of the neuraminidase inhibitor Zanamivir in the treatment of influenza A and B virus infections." J. Infect. Dis. 180: 254-261.

83. Higuchi ML et al., 1997, "Association of an increase in CD8+ T cells with the presence of *Trypanosoma cruzi* antigens in chronic, human chagasic myocarditis," Am. J. Trop. Med. Hyg. <u>56</u>:485-489.

84. Higuchi ML et al., 1987, "The role of active myocarditis in the development of heart failure in chronic Chagas' disease: a study based on endomyocardial biopsies," Clin. Cardiol. 10:665-670.

85. Libby P et al., 1986, "A neuraminidase from *Trypansosoma cruzi* removes sialic acid from the surface of myocardial and endothelial cells, "J. Clin. Invest. 77:127-135.

86. Soleslavsky O. et al., 1968, "Adsorption of *Mycoplasma pneumoniae* to neuraminic acid receptors of various cells and possible role in virulence." J. Bacteriol. <u>96(3)</u>:695-705.

Citation of these references is not an admission that any one is prior art against the present invention.

Please charge the fee due for this submission to Deposit Account No. 02-4377. A copy of this paper is enclosed.

Respectfully submitted, BAKER/BOTTS L.L.P.

Lisa B. Kole

PTO Reg. No. 35,225

212-408-2628

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. 068528.0103	Serial No. 10/086,913	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant: Higuchim, et al.		
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U.S. PATENT DOCUMENTS					
Document No.	Date	Name	Class	Subclass	Filing Date if Approximate.
	Document No.	Document No. Date	Document No. Date Name	Document No. Date Name Class	Document No. Date Name Class Subclass

	FOREIGN PATENT DOCUMENTS						
Exam Initial	No.	Document No.	Date	Country	Class	Subclass	<u>Translation</u> Yes No

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
		"A Side effect of neuraminidase inhibitor in a patient with liver cirrhosis" by Kaji, et al. <u>J. Infect. Chemother</u> , (2005)(11:41-43)
		"Structural Insights into the catalytic mechanism of Trypanosoma cruzi trans-sialidase" by Amaya, et al., Structure, Vol. 12, pp. 775-784, May 2004
		"Trypanosoma cruzi trans-sialidase as a new therapeut tool in the treatment of chronic inflammatory diseases: possible action against mycoplasma and chlamydia" by Higuchi, Medical Hypotheses (2004)(63, 616-623).

NY02:531905.1	
Examiner	Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. 068528.0103	Serial No. 10/086,913	
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	Examiner: Maryann Monshipouri		

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		"Coinfection with mycoplasma pneumoniae and chlamydia pneumoniae in ruptured plaques associated with acute myocardia infarction" by Higuchi, et al., Arq. Bras Cardiol, Vol. 81, No. 1, 12-22, 2003.
		"Pathophysiology of the heart in chagas' disease: current status and new developments" by Higuchi, et al., 2003 European Society of Cardiology, pp. 96-107
		"Trypanosoma cruzi trans-sialidase operates through a covalent sialyl-enzyme intermediate: Tryosine is the catalytic nucleophile" by Watts, et al., J. Am. Chem. Soc. 2003, 125, 7532-7533.
		A possible role for complement in the pathogenesis of chronic chagasic cardiomyopathy" by Aiello, et al., Journal of Pathology, 2002, 197; 224-229
		The Crystal Structure and Mode of Action of Trans-sialidase, a key enzyme in trypanosoma cruzi pathogenesis by Buschiazzo, et al., Molecular Cell, Vol. 10, 757-758, Oct. 2002
		Intracellular DNA replication and long term survival of pathogenic mycoplasmas" by Dallo, et al., Microbial Pathogenesis, 2000, 29: 301-309
		Systematic mapping of hearts from chronic chagasic patients: the association between the occurrence of histopathological lesions and Trypanosoma cruzi antigens" by Palomino, et al., Annals of Tropical Medicine and Parasitology, Vol. 94, No. 6, 571-579 (2000).
		Efficacy and Safety of the Oral Neuraminidase Inhibitor Oseltamivir in Treating Acute Influenza by Treanor, et al., JAMA, Feb. 23, 2000, Vol. 283
		Efficacy and Safety of the Neuraminidase Inhibitor Zanamivir in the treatment of Influenza A and B Virus Infections by Monto, et al., Journal of Infectious Diseases, 1999: 180; 254-61.
		Association of an increase in CD8+ T cells with the presence of trypanosoma cruzi antigens in chronic human chagasic mycoarditis by Higuchi, et al., Am. J.Trop. Med. Hyg., 56(5), 1997, pp. 485-489

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		The role of active myocarditis in the development of heart failure in chronic chagas disease: a study based on endomycardial biopsies by Highuci, et al., Clin. Cardiol. 10, 665-670 (1987)
		A Neuraminidase from Trypanosoma cruzi removes sialic acid from the surface of mammalian myocardial and endothelial cells by Libby, et al., J. Clin. Invest., Vol. 77, Jan. 1986, 127-135
		Adsorption of Mycoplasma pneumonia to neuraminic acid receptors of various cells and possible role in virulence by Sobeslavsky, et al. Journal of Bacteriology, Sept. 1968, p. 695-705.
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